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July 8, 2004

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20857

Re: Docket No. 2004N-0133 --
Questions and Comments on 21 C.F.R. Part 11 Revisions

Dear Sir or Madam:

United Parcel Service, Inc. ("UPS") offers the following questions and comments as the Food and Drug Administration ("FDA") reconsiders the requirements of 21 C.F.R. Part 11 ("Part 11").

UPS is the world's largest package delivery company and a global leader in supply chain services, offering an extensive range of options for synchronizing the movement of goods, information, and funds. Headquartered in Atlanta, Georgia, UPS serves more than 200 countries and territories worldwide. UPS stock trades on the New York Stock Exchange (UPS), and the company can be found on the Web at UPS.com. The Company has encountered Part 11 compliance issues in various operating divisions, including its core small package carrier operations and, more extensively, in the operations of UPS Supply Chain Solutions, Inc. (UPS-SCS). The latter is a third party logistics provider of warehousing, distribution, and other services to a significant FDA-regulated clientele.

As a leading developer and employer of electronic data capture and transmission technologies, UPS appreciates the critical importance of system validation and control. As we have striven to integrate Part 11 into our business model, however, we have identified areas in which clarification or streamlining of the regulatory requirements is clearly warranted.

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Boundaries of Part 11 Obligations. We first ask that FDA clarify the extent to which Part 11 applies to the operations of third party logistics service providers. Although we understand fact-specific analysis will be required in any particular circumstance, it would be beneficial if FDA will discuss its expectations in areas such as the following:

- Where do compliance obligations start and stop when multiple companies' systems, or even multiple systems within a company, interface? For example, if a third party logistics provider offers a software-based system that receives order fulfillment directions from a medical device or pharmaceutical client's electronic system, what aspects of the logistics provider's system must be

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validated or otherwise comply with Part 11? If the logistics provider transmits to its customer electronic information concerning distributions made, what aspects of the logistics provider's system are affected? It is difficult to discern FDA's position from the current Part 11 regulations and related guidance.

- Is it correct that only portions of electronic systems that *directly* support the creation, transmission, or maintenance of electronic records are subject to validation and other Part 11 requirements? For example, if order or distribution data are transmitted from a medical device or pharmaceutical client's proprietary computer system to a carrier's system, or vice versa, the data may move through various "parking spaces" (e.g., different servers, different spots on the same server, handshake protocols, and uploads with other systems that copy or take pictures of such information; transmission of data via wireless devices on a different proprietary system, and later coupling data with a captured handwritten signature to an electronic display pad; uploading the data and signature file). Is it correct that Part 11 obligations strictly follow the intended use of electronic information for regulated purposes, and do not apply to related systems (even if they capture the same information for non-regulated purposes)?

Application of Part 11 to Legacy Systems. Please describe in significant detail how FDA intends to regulate legacy systems. UPS has particular interest to understand how legacy elements are regarded when they comprise part of a larger electronic system (some of which may have been installed and activated after the 1997 "legacy" cut-off).

What information and documentation (e.g., system specifications, testing, etc.) must be developed and maintained to support a conclusion that both the legacy system and the overall system (to the extent they may be different) are under adequate control? Will compliance be judged from a bright-line date or other measurement? How (if at all) must the owner of a system with legacy elements respond, for example, if past software development practices or change controls did not strictly follow the model in FDA's "General Principles of Software Validation" guidance or fully consider the control and security measures identified in current Part 11? How can one document a legacy system compliance analysis in a manner acceptable to FDA?

Risk Assessment. FDA spoke in very general terms in its September 2003 guidance about applying risk assessment to decisions whether to implement certain Part 11 requirements. Similarly, FDA now asks whether the use of risk mitigation and appropriate controls can eliminate concerns regarding legacy systems.

It is not clear in the first place what threshold of risk should correlate with implementation of Part 11 requirements, and then how requirements should be applied. For example, if an order management/distribution record system may be used to facilitate product recalls, does that correlate to a low, medium, or high risk to product quality or safety? Does it correlate to a low, medium, or high risk to record quality? What factors into these determinations? Without greater guidance from FDA on how to apply risk mitigation and appropriate controls in defined examples, risk assessment and risk mitigation are just words that suggest that there may be a sliding scale.

FDA must define more clearly in regulations, preamble examples, and/or guidance what specifically needs to be done on a moving-forward basis for legacy systems that create, modify, store, etc., electronic records and/or signatures that are intended in whole or in part to satisfy predicate rule requirements. Use of detailed illustrative examples for satisfying requirements of the rule, such as an

audit trail requirement for a given hypothetical system of FDA's choosing, would be extremely useful to industry.

Validation Best Practices. We respectfully request that FDA publish a thorough best practices guidance concerning validation (e.g., identify the components of a good plan).

Revision of Definitions. FDA inquired whether revision to definitions in Part 11 would be useful and help clarify the agency's narrow approach to implementation. UPS recommends that FDA indeed revise or clarify several definitions in current Part 11 to address and be consistent with how the agency intends to define the scope of Part 11.

Specifically, definitions for "closed systems" and "open systems" should be clarified with respect to whether the two are mutually exclusive, or merely segments of a spectrum. For example, does a "closed system" label apply only to a main application or software system, or does it encompass all piggyback systems that link or interface with the main system in any way?

Similarly, the definition for what constitutes an "electronic record" should be modified to move beyond the catch-all language presently used, to reflect the limited scope of records that are used to fulfill predicate rule requirements. Clear distinction also should be made between "typewriter"-type electronic activities and electronic data capture that is used directly to fulfill in whole or part predicate rule requirements.

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UPS requests and looks forward to significant FDA clarification concerning obligations under 21 C.F.R. Part 11. Thank you for factoring these comments into the agency's review.

Sincerely,

Robert A. Bergman
Vice President, Public Affairs